United States Environmental Protection Agency

Human Health Risk Assessment (HHRA) Research Program

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SAB/BOSC Meeting
July 10-11, 2012

EPA United States Environmental Protection Agency

Outline

- **2012 SAB/BOSC charge questions**
- **Strategic plan overview**
- **First year progress**
  - Products and impacts
  - Innovation in human health assessments
  - Stakeholder engagement and communication
  - Integration across ORD research programs
- **Goals for the coming year**

2012 SAB/BOSC Charge Questions

- The HHRA research program is committed to modernizing methods to evaluate the health effects of pollutants, consistent with advice of the SAB/BOSC and National Academy of Sciences. What aspects of the hazard and dose-response assessments produced by the HHRA research program are most likely to benefit from the application of state-of-the-art data streams and methods (e.g., in vitro toxicity testing results, gene expression profiling data, bioinformatics and QSAR modeling)?

- In the 2010 mid-cycle progress review of the HHRA program the Board of Scientific Counselors noted that "IRIS assessments and ISAs are among the most heavily peer reviewed documents provided by scientists anywhere." How can the HHRA research program efficiently obtain robust peer reviews that contribute to the scientific integrity of assessments without impacting the timely provision of documents with public health value? Additionally, can the SAB/BOSC provide advice on the appropriate overall balance of peer review of individual products versus other recommended scientific capacity-building activities?

Peer Review Guidance Informs HHRA Research Strategy

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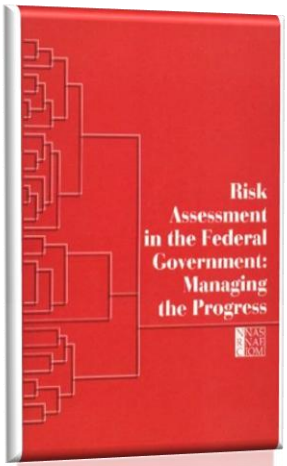
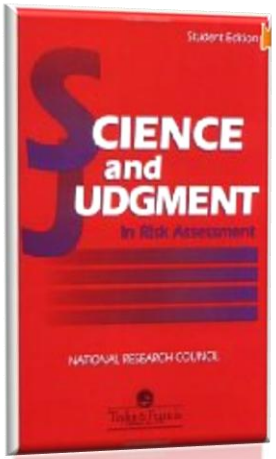
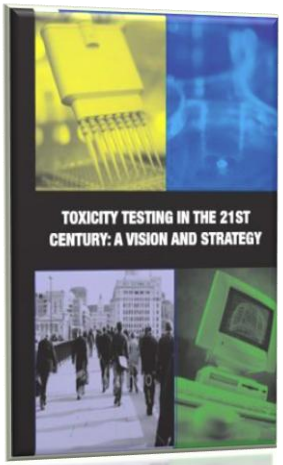
NRC GUIDANCE:



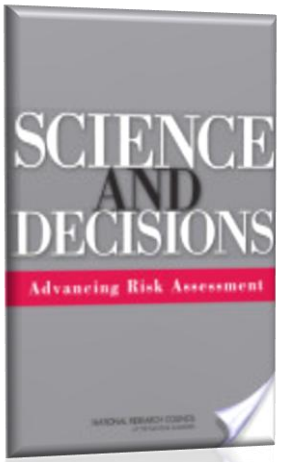
1983



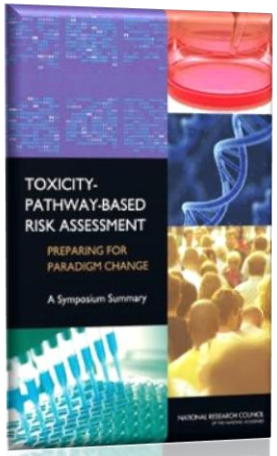
1996



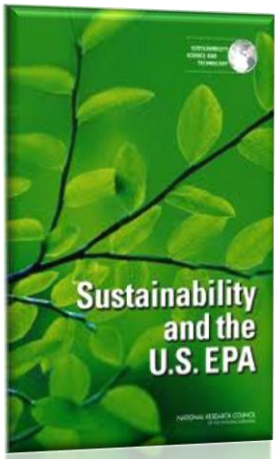
2007



2009



2010



2011

SAB-BOSC GUIDANCE:

- **Problem formulation**: Alignment with end-user needs
- **Science integration and innovation**: Foster integration of ORD's innovative work into decision-making
- **Communication and outreach**: Earlier, broader engagement with risk assessment, stakeholder and scientific communities

IMPLEMENTATION:

HHRA STRATEGIC ACTION PLAN

HHRA Strategic Research Action Plan: Overview

PROBLEM STATEMENT

EPA's decisions must be based on scientifically-defensible evaluations of data that are relevant to assessing human health impacts. The current demand for human health assessments of individual chemicals and chemical mixtures is not being fully met.

VISION

The HHRA research program will generate timely, credible human health assessments of individual chemicals and chemical mixtures to support priority EPA risk management decisions, thereby enabling EPA to better predict and prevent risk.

HHRA Strategic Research Action Plan: Four Themes

- **Theme 1**: Integrated Risk Information System (IRIS) health hazard and dose response assessments
- **Theme 2**: Integrated Science Assessments (ISAs) of criteria air pollutants
- **Theme 3**: Community Risk and Technical Support for exposure and health assessments
- **Theme 4**: Modernizing Risk Assessment Methods

First Year Progress: Integrated Risk Information System (IRIS) Milestones

Final assessments recently posted:

- Urea: July 2011
- Trichloroacetic acid (TCA): September 2011
- Hexachloroethane: September 2011
- Trichloroethylene (TCE): September 2011
- Dichloromethane (DCM): November 2011
- Tetrachloroethylene (PERC): February 2012
- Tetrahydrofuran: February 2012
- Dioxin, noncancer: February 2012

Draft assessments recently released for public comment and external peer review:

- n-Butanol: August 2011
- 1,4-Dioxane, inhalation: August 2011
- Libby amphibole asbestos: August 2011
- Biphenyl: September 2011
- Vanadium pentoxide: September 2011
- Ammonia: June 2012
- Trimethyl benzenes: June 2012

First Year Progress:
Integrated Risk Information System (IRIS) Impacts

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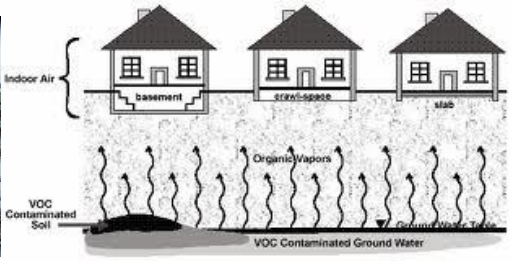
- **IRIS values are used by:**
  - EPA's program offices and regions
  - States
  - Local health agencies
  - International organizations
  - Other federal agencies

- **IRIS values support clean-up decisions and standard-setting across the US**
- **Examples:**
  - Contaminated sites: Dioxin, TCE, PERC
  - Air, vapor intrusion: TCE, PERC, DCM
  - Drinking water: assessment of multiple carcinogenic VOCs by Office of Water (TCE, PERC, DCM)
  - Cumulative assessment of effects on communities
  - 2012 TSCA workplan (TCE, DCM)



First Year Progress:
Integrated Science Assessments (ISAs)

ISA milestones:

- 1st draft lead ISA (July 2011)
- 2nd draft ozone ISA (September 2011)
- 2nd draft lead ISA (December 2011)
- 3rd draft ozone ISA (June 2012)

Impacts:

- ISAs support regulatory decisions on primary and secondary National Air Quality Standards
- Multi-pollutant Science Assessment framework supports future research, assessment and policy developments

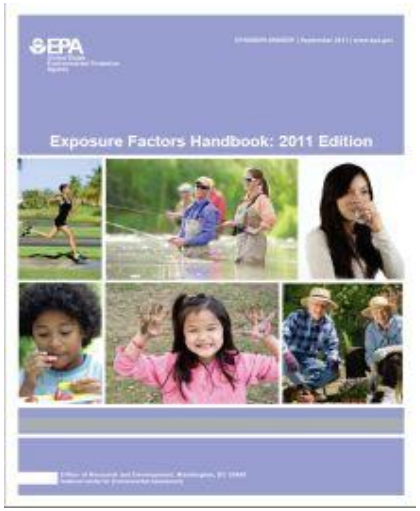
First Year Progress: Community Risk and Technical Support

Milestones:

- Exposure Factors Handbook:
  - 2011 Edition: September 2011
  - Highlights (short report): October 2011
- Numerous PPRTVs completed
  - Example: Sulfolane (supports clean-up in Alaska)
- Rapid exposure and risk assessment
  - Example: evaluation of human health and ecological impacts of PAHs from parking lot sealants (jointly with SSW)

Impacts:

- Enables program and regional offices to address a variety of community needs



Innovation: Application of Health and Environmental Research Online (HERO)

- **HERO– a database of scientific studies used to develop EPA risk assessments**
  - Originally created for the ISA program
  - Expanded to support IRIS and PPRTV assessment development
- **HERO is**:
  - Transparent (accessible by peer reviewers and the public)
  - Flexible (searchable by topic or assessment)
  - Efficient (in literature retrieval, citation, and documentation)
- **HERO is an *EVERGREEN* database – new studies are continuously added**

www.epa.gov/hero

Innovation: Support for Economic Health Benefits Analyses

- **Characterizing chemical dose-response in a manner that can be applied in economic health benefits analyses, in response to end-users, NAS and SAB/BOSC:**
  - Non-cancer effects of formaldehyde
  - Adult neurological effects of elemental mercury
  - Effects of adult lead exposure
  - Adverse birth outcomes
- **Collaboration with EPA end-users and economists**
- **Ongoing program office engagement coordinated by newly-formed "Morbidity Workgroup" (lead by National Center for Environmental Economics, Office of Policy)**

HHRA Coordinates with Internal and External Partners

- US Environmental Protection Agency, Program Offices and Regions
- National Institutes of Environmental Health Sciences & National Toxicology Program
- Centers for Disease Control and Prevention
- Agency for Toxic Substances and Disease Registry
- NIH Chemical Genomics Center
- California's Environmental Protection Agency, Office of Environmental Health Hazard Assessment
- FDA National Center for Toxicological Research
- Department of Defense
- Environmental Council of the States (ECOS)
- Interstate Technology and Regulatory Council (ITRC)

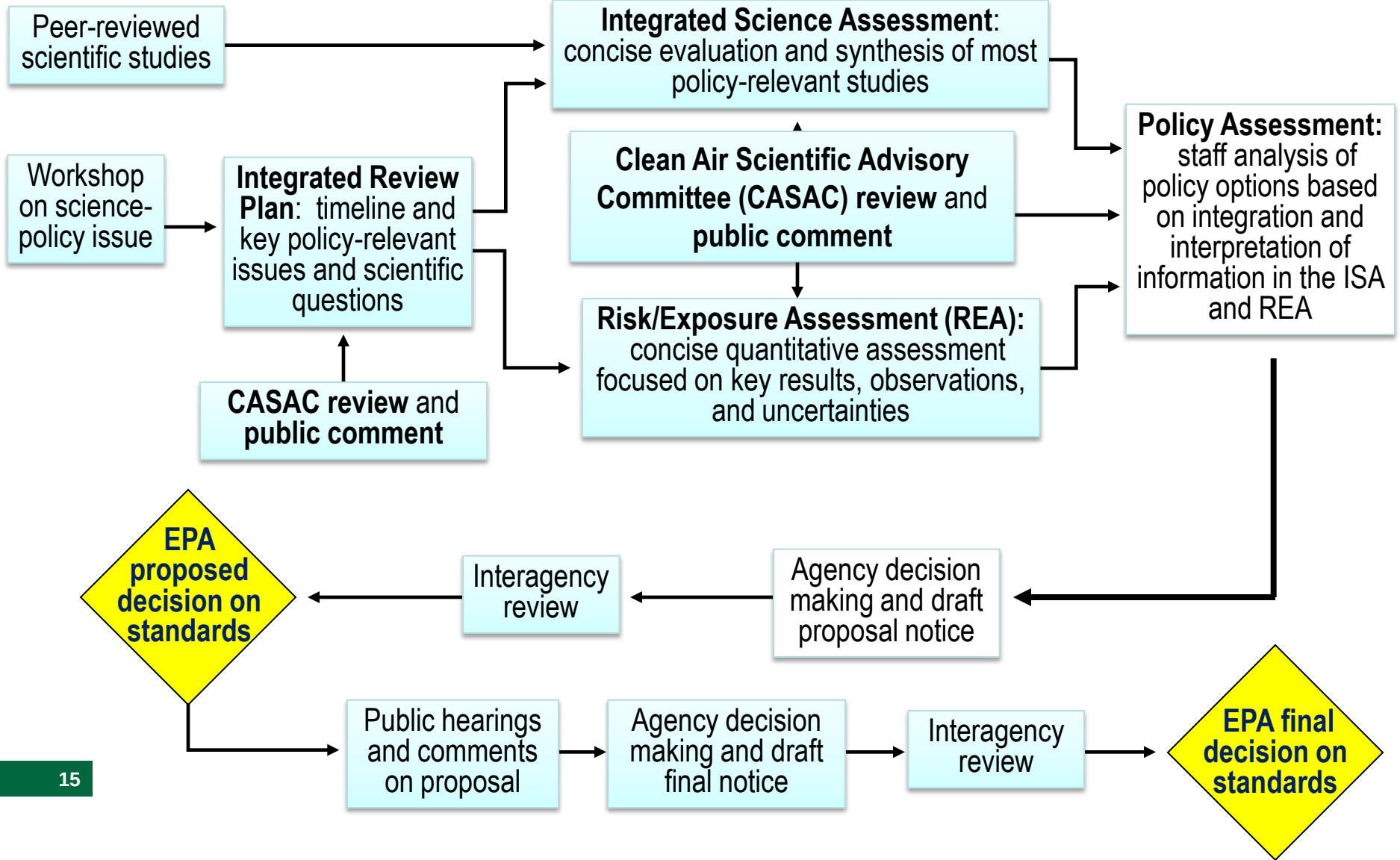
Stakeholder Engagement:
International Efforts

- **Harmonization of approaches**: Cooperative agreements with World Health Organization (WHO) committees on Public Health & Environment and International Program on Chemical Safety (IPCS)
- **Contributing scientific expertise on carcinogen risks**: International Agency for Research on Cancer (IARC) review panel participation
- **Education and outreach**: Risk assessment training for developing countries (South Africa, Ghana, Saudi Arabia, Egypt, Thailand, and others)

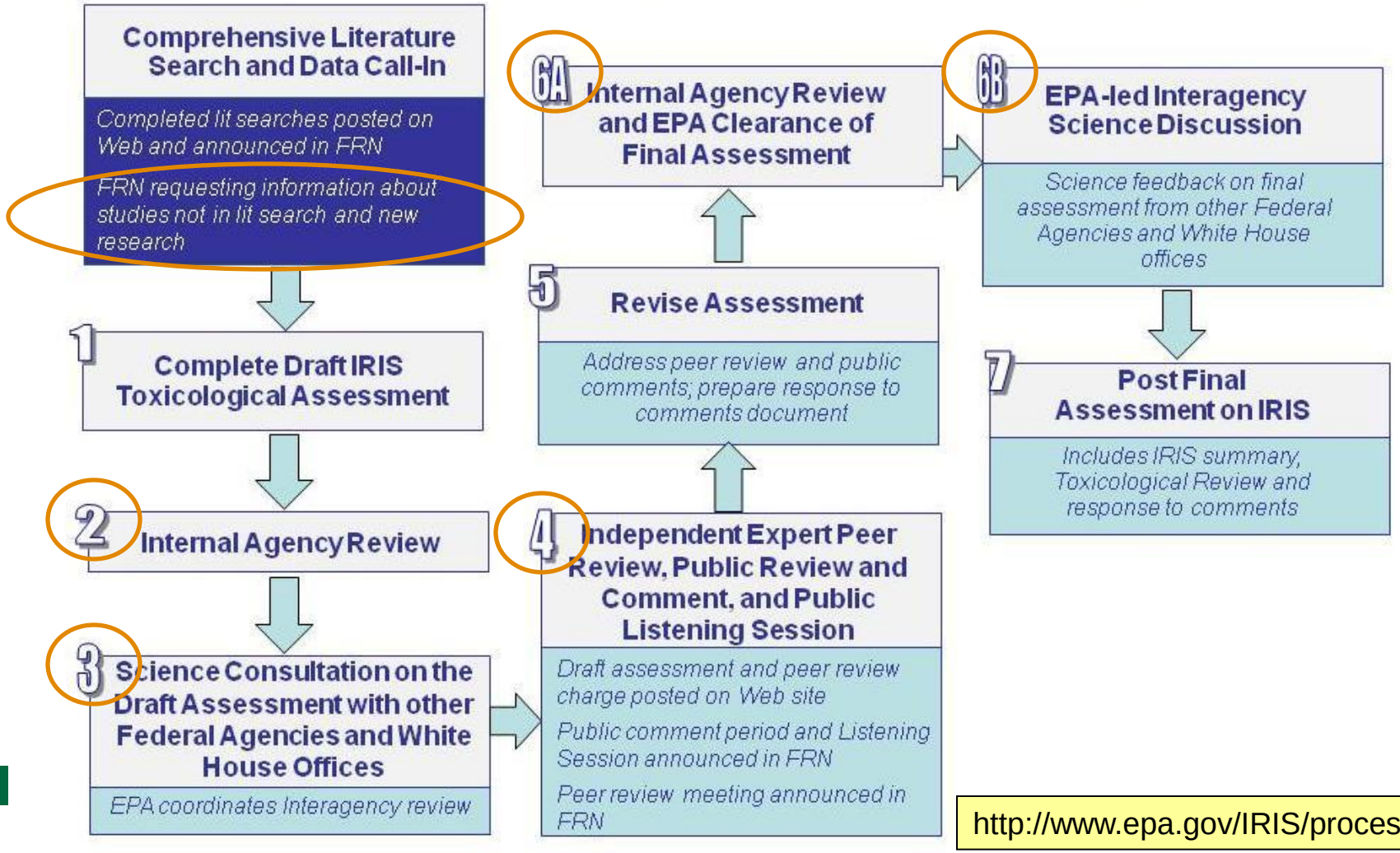
Stakeholder Engagement: International Risk Assessment Training

- **In cooperation with EPA's Office of International and Tribal Affairs and the U.S. Department of State, HHRA**:
  - **Saudi Arabia** – May 2012: Provided risk assessment training to participants of the Saudi International Environmental Technologies Conference.
  - **Bangkok, Thailand** – Sept. 2012: Will provide risk assessment training and represent NCEA at the 8th Congress of Toxicology for Developing Countries (http://www.thaitox.org/8ctdc/)
  - **Egypt** – February 2013: Will provide risk assessment training to scientists from Africa and the Middle East during an international conference on toxicology and risk assessment challenges.
  - **Seoul, South Korea** – July 2013: Will provide risk assessment training and hold a symposium on the international importance of the IRIS program during an International Congress of Toxicology meeting.

Stakeholder Engagement: Opportunities for Input during Integrated Science Assessment Development



Stakeholder Engagement: Opportunities for Input during IRIS Assessment Development



http://www.epa.gov/IRIS/process

Stakeholder Engagement: Mechanisms for IRIS External Peer Review

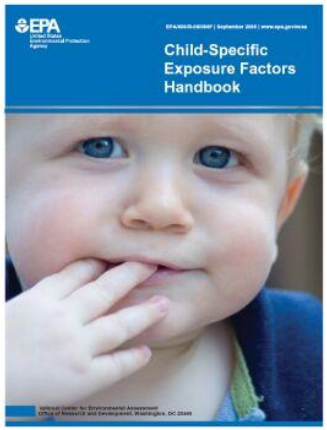
- **Panel and Letter Peer Review**
  - Assessment-specific review conducted by EPA contractor
- **Dedicated Chemical Assessment Advisory Committee**
  - Science Advisory Board purview
  - EPA's consultations will seek:
    - Peer review of selected IRIS assessments; and
    - Advice on implementation of 2011 NAS recommendations
- **NAS Review**
  - Mandated by 2012 Consolidated Appropriations Act
  - NAS review of IRIS assessment development process, arsenic IRIS assessment

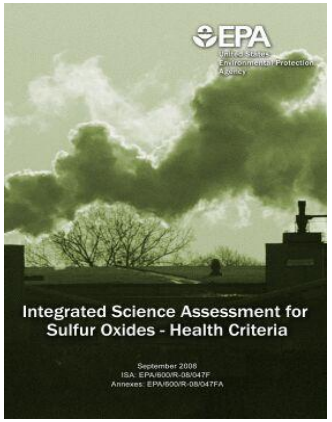
Stakeholder Engagement: Program and Regional Outreach and Communication

- Examples of engagements with program and regional offices include:
  - Hosting regular coordination meetings with program and regional partners (*e.g.*, weekly meetings between HHRA's Integrated Science Assessment team and Office of Air Quality Planning and Standards)
  - Engaging programs and regions in nominating and prioritizing chemicals for IRIS assessment
  - Providing programs and regions with timely reports on HHRA progress, and soliciting feedback
  - Communicating changes in the schedule or scope of high impact HHRA outputs as they arise
  - Providing consultation (e.g., estimation and evaluation of exposures and human health risks to PCB exposures in schools)

Integration across ORD Programs

- **ORD research products are integrated into assessments developed by HHRA**
- **Examples of cross-program synthesis products include:**
  - Exposure Factors Handbook and Child-Specific Exposure Factors Handbook – *Sustainable and Healthy Communities (SHC); Safe and Sustainable Water Resources (SSWR)*
  - IRIS health assessments – *SSWR; SHC; Air, Climate and Energy (ACE); Chemical Safety and Sustainability (CSS)*
  - Provisional Peer Reviewed Toxicity Values (PPRTVs) – *SHC, CSS*
  - Integrated Science Assessments – *ACE, SHC*
  - Cumulative Risk Assessment – *ACE, SHC, SSWR, CSS, and Homeland Security Research (HSR)*
  - New Methods, Models and Approaches in Risk Assessment– *CSS (home of NexGen assessments and nanotechnology initiative), ACE, SSWR, SHC, and HSR*
  - Cross-agency research plan for hydraulic fracturing– *ACE, SSWR*





Integration with ORD Programs: Key Cross-Cutting Topic Areas

- Nitrogen
- Children's health/environmental justice
- Non-monotonic dose response
- Applying new chemical assessment approaches in human health risk assessment (HHRA-CSS)

Goals for Upcoming Year: Strengthening the IRIS Program

Process and product improvements per 2011 NAS recommendations:

- Preamble to each IRIS assessment describes methods and criteria
- HERO database supports literature collection and review (see slide #9)
- Clear and transparent presentation of data, analyses and conclusions
- Methodological improvements (*e.g*, systematic literature reviews, weight of evidence evaluation approaches)

Earlier peer and stakeholder consultation:

- For certain individual assessments
- Workshops on some key science issues (*e.g*., mouse lung tumors)

Alignment with user needs:

- Enhance timeliness of priority assessment
- Clearly communicate scope and timeline with users and public
- Provide outputs to inform a broader range of end-user analyses (*e.g*., of cumulative and community risk, economic health benefits, sustainability)

Goals for Upcoming Year: Science Integration and Innovation

Key issues (identified by a 2010 colloquium of EPA's Risk Assessment Forum) will continue to drive change in assessment approaches, methods, and outputs:

- Address risks from chemicals currently lacking toxicity values
- Expand the ability to calculate economic benefits of improving human health through exposure reduction
- Move beyond single chemical/stressor-based assessments

Human Health Risk Assessment Colloquium Summary Report*:*
http://www.epa.gov/raf/human-health.htm

HHRA Research Program Summary

- HHRA will continue to provide high priority assessments while implementing process efficiencies and product quality improvements, including per 2011 NAS recommendations

- Collaboration with Agency, federal, state, regional, national, and international partners in the scientific and risk assessment communities is essential to ensure scientific integrity–and applicability–of HHRA products

- Science integration and innovation will enable HHRA to continue to meet stakeholder needs, and to make progress towards unmet challenges in evaluating human health and sustainability impacts